

Substitute for form 1449/PTO  <h2 style="text-align: center; margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; margin: 5px 0;">(Use as many sheets as necessary)</p>			<b>Complete if Known</b>		
Application Number	10/623,431				
Filing Date	July 18, 2003				
First Named Inventor	Jay D. KRANZLER et al.				
Art Unit	1614				
Examiner Name	Alicia R. HUGHES				
Attorney Docket Number	20269/1201776-US2				
Sheet	1	of	2		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/AH/	A1	5,532,268	07-02-1996	Wong et al.	
/AH/	A2	5,912,256	06-15-1999	Koch et al.	
/AH/	A3	6,602,911	06-05-2003	Kranzler et al.	
/AH/	A4	6,635,675	10-21-2003	Kranzler et al.	
/AH/	A5	6,992,110	01-31-2006	Kranzler et al.	
/AH/	A6	US 2002/0010216	01-24-2002	Rogosky et al.	
/AH/	A7	US 2003/0082214	05-01-2003	Williams et al.	
/AH/	A8	US 2003/0082225	05-01-2003	Mason	
/AH/	A9	US 2004/0034101	02-19-2004	Rao et al.	
/AH/	A10	US 2005/0032782	02-10-2005	Rao et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>4</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/AH/	B1	EP 0 814 084	12-29-1997	Eli Lilly and Company	
/AH/	B2	EP 0 818 198	01-14-1998	Lilly S.A.	
/AH/	B3	WO 97/10816	03-27-1997	Eli Lilly and Company	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 801.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
/AH/	C1	Fuller, Clinical Applications of 5-HT Uptake Inhibitors, Advances in the Biosciences, Vol. 85, pgs. 255-270, 1992.			
/AH/	C2	Lecrubier, Milnacipran: The Clinical Properties of a Selective Serotonin and Noradrenaline Reuptake Inhibitor (SNRI), Human Psychopharmacol. Clin., Vol. 12, pgs. S127-S134, 1997.			
/AH/	C3	Farthing, New Drugs in the Management of the Irritable Bowel Syndrome, Drugs, Vol. 56, pgs. 11-21, 1998.			
/AH/	C4	O'Malley, et al., Treatment of Fibromyalgia with Antidepressants, J. Gen. Intern. Med., Vol. 15, pgs. 659-666, 2000.			
/AH/	C5	Mertz, Irritable Bowel Syndrome, N. Engl. J. Med., Vol. 349(22), pgs. 2136-2146, 2003.			
/AH/	C6	Fennerty, Traditional Therapies for Irritable Bowel Syndrome: An Evidence-Based Appraisal, Rev. Gastroenterol. Disord., Vol. 3, Suppl. 2, pgs. 18-24, 2003.			

Examiner Signature	/Alicia Hughes/	Date Considered	03/15/2009
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			Art Unit	1614	
			Examiner Name	Alicia R. HUGHES	
Sheet	2	of	2	Attorney Docket Number	20269/1201776-US2

/AH/	C7	Patel, et al., The Placebo Effect in Irritable Bowel Syndrome Trials: A Meta-Analysis, Neurogastroenterol. Motil., Vol. 17, , pgs. 332-340, 2005.	
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Examiner Signature	/Alicia Hughes/	Date Considered	03/15/2009
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